REMARKS

Application Status

Claims 1 and 2 are pending, and were rejected. Claims 3-6 are method claims, which were withdrawn pursuant to a restriction requirement. New claims 7-19 are added as discussed below, and claim 2 was amended. No new matter is added by these amendments.

Objections to the Specification

(a) The specification included a text string resembling a URL, and was objected to on this basis. The corresponding paragraph has been amended as suggested by the Examiner to remove 'http://' from that text string.

(b) The Examiner suggested a more descriptive title was needed; the Amendment introduces the title suggested by the Examiner.

Objections to the Abstract

The Examiner objected to the Abstract "for not completely describing the disclosed subject matter (see M.P.E.P. 608.01(b))."

A more detailed Abstract is submitted herewith, which complies with the MPEP requirement to describe "the nature and gist of the technical disclosure."

The amendments add no new matter. Entry of these amendments is respectfully requested.

Claim Objections

Claim 2 was objected to because 'ccr' and 'icm' were used without spelling out the terms to which they refer. While the applicant believes these terms are entirely clear to a person of ordinary skill in the context of the claims, claim 2 was amended to spell out each of these terms in

order to remove the objection. The amendment is supported by the specification at page 12, lines 9-11, and at page 58, lines 6-7 combined with the cited references in that line that provide article titles describing isobutyryl-CoA mutase.

New claims 7-19 have been added. These claims are supported throughout the specification, and are specifically supported as follows:

Claim 7: pg. 14, lines 11-14

Claim 8: pg. 14, lines 11-17

Claim 9: pg. 14, lines 5-7

Claim 10: pg. 12, lines 22-29

Claim 11: pg. 12, lines 10-11

Claim 12: pg. 57, lines 25-26

Claim 13: pg. 13, lines 1-2

Claim 14: pg. 13, lines 1-2

Claim 15: pg. 13, lines 1-2

Claim 16: pg. 11, lines 27-28

Claim 17: pg. 5, lines 1-3

Claim 18: pg. 5, lines 3-4

Claim 19: pg. 5, lines 4-5.

No new matter is added by these amendments. Entry of the amendments and reconsideration in view of the following comments is requested.

Information Disclosure Statement

The applicant appreciates acknowledgment of the IDS previously submitted, and consideration of the references listed thereon. The applicant also appreciates being advised that several of the references that were submitted with an earlier IDS (Form PTO-1449) were missing from the PTO files and could not be considered. A copy of the IDS previously submitted is included with this response along with a new copy of each of the missing references. The applicant would appreciate consideration of those references by the Examiner, and requests a signed copy of the clean copy of the IDS, marked to indicate these references were considered.

Claim Rejections under 35 U.S.C. 101

The Examiner asserts that claim 2 recites non-statutory subject matter, because the claimed host cell "reads on a product of nature."

The applicant traverses this rejection: claim 1 uses the term 'recombinant' in describing genes in the claimed cell in two places. As such, one of ordinary skill would not interpret the claim to cover a product of nature, it would be understood to refer to an artificially modified cell. The modification of the cells is inherent in the description of their 'recombinant' components. The applicant is not required to recite that which is inherent and is clearly conveyed by the claim language, or to add steps to indicate 'the hand of the inventor' expressly. For example, 'Element 95' is a patent claim that recites only an elemental substance, with no mention of its synthetic source, which was apparent to those skilled in the art. *See In re Seaborg*, 328 F.2d 996 (CCPA 1964); U.S. Patent No. 3,156,523. Similarly, no amendment is necessary for one of ordinary skill to recognize that claim 2 does not describe a product of nature, because it requires recombinant genes. Withdrawal of this rejection is respectfully requested.

Claim Rejections under 35 U.S.C. 112

The Examiner rejected claims 1-2 because the source of the ccr and icm genes was not identified in the claim. The Examiner further asserted that the claims rely on functional language and do not describe the claimed subject matter "by structural properties per se. It is noted that the specification provides specific sequences, however none is recited in the claims....a biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." According to the Examiner, "the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed."

The applicant traverses this rejection.

First, the Examiner concedes that the specification provides sequences, but alleges that written description is lacking. This seems self-contradictory. Stating that the claims use functional properties relates to the language of the claims, not the adequacy of the written description. The Examiner says that the claims do not set forth the organism from which each gene comes, so one "cannot envision the detailed chemical structure encompassed in the claims." However, there is no per se rule that a sequence is required, even in the specification, to support a claim, and no rule that a claim must use a sequence. Claims must convey their scope to a person having ordinary skill in the art, and this is often best done using the same language that is used in the art. The recitation of a sequence for a gene is not required to meet the written description standard. *Falkner v. Inglis*, BPAI Case No. 05-1324, (Interference No. 105,187), pg. 14 (May 26, 2006). ("there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.") In Falkner, the Board confirmed that where the prior art teaches what the applicant refers to, no sequence or structural description is needed in the specification, let alone in the claims. Neither recitation of the sequences nor incorporation by reference is necessary where what the application refers to is known.

The Examiner cited *Lockwood v. American Airlines*, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). However, the problem in that case was that, "Lockwood claimed a distinct invention from that disclosed in the specification." *Id.* at 1966. Here, the invention in the claims is the same as that described in the specification, which clearly distinguishes this situation from that in *Lockwood.*

The Examiner's objection seems to suggest that the claims should name, and thus be limited to, the precise embodiments set forth in the specification, by naming those specific sequences. However, claims should not be limited to the disclosed species, as long as a person of ordinary skill can ascertain the scope of the claim and envision that the inventor was in possession of the claimed subject matter, based on what the specification discloses. The examples in the specification describe certain embodiments of the invention, thus they enable it to be practiced; but those examples do not define the scope of the invention, so the applicant should not be required to limit the scope of the claims to that represented by the examples.

This specification provides representative examples of the sequences and sources for the gene segments required to form the claimed constructs. The prior art, including the reference cited in the art-based rejection in this Office Action (Kuhstoss, et al., Gene vol. 183, 231-36 (1996)), clearly demonstrate that the claim terms used herein are routinely used and understood by those skilled in the art to describe known genes. Moreover, the claim limitations are not "described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence", as the Examiner asserts, because the functional descriptions relate to genetic sequences that are known and understood in the art. The specification discusses, for example, the known structural characteristics of AT domains. (Page 20, lines 24-29).

The specification states that *icm*, for example, refers to the *icmA* and *icmB* genes (see page 13, line 2, "the *icmA* and *icmB* genes (hereinafter referred to as the *icm* gene)..."); according to the Examiner, *icmA* and *icmB* are recognized in the art (Office Action at page 5, "the art recognizes *icmA* and *icmb*"). Thus the claim term *icm*, read in view of the specification, represents *icmA* and *icmB*, which are understood in the art.

The claims do not set forth which specific source is used for the *ccr* gene, as the Examiner noted. However, the specification says, "The gene (*ccr*) encoding this enzyme can be isolated from *Streptomyces coelicolor* and other host cells." Page 12, lines 10-11. Thus the specification indicates an exemplary source and the possibility of obtaining the material from other sources, and alternative sources for *ccr* were well known in the art; indeed, *ccr* "is common to most streptomycetes", according to Liu, et al., *Metabolic Engineering*, 3, 40-48 (2001) (abstract) **(Exhibit A)**. Thus the term is well understood, and describes genes that are known. The applicant need not set forth that which is well known in the art.

Claims must be read in view of the specification, from the perspective of a person of ordinary skill in the art. The terminology used in these claims is supported by the specification; moreover, it is standard terminology used by those skilled in the art to describe well-known materials, as is evident from the cited reference, Kuhstoss, et al., Gene vol. 183, 231-36 (1996), which uses the same terminology. The applicant should not be required to limit the claims to the disclosed sources of these materials, when the materials were well known in the art, and the invention resides not in the specific sources of the materials, but in the novel combination of them.

It is perfectly acceptable to describe a claimed antibody, for example, by reference only to the substance to which it binds, a function of the antibody rather than a structural feature of it. As with antibodies, the well-known claim elements "KSQ domain", "AT specific for ethylmalonyl CoA" and "an ACP domain" are clear terms to those skilled in the art, and are descriptive of known materials; adding a description of the organism from which a gene is derived, as suggested by the Examiner, would add no structural information to the claim, and it would unduly limit the claim based on the examples, rather than encompassing the inventive concept that would be understood by one skilled in the art in view of the claim language used.

The Examiner also cited MPEP 2163, when stating that a known amino acid sequence does not describe the native, naturally occurring mRNA or DNA nucleic acid sequence. That seems irrelevant, though: the Federal Circuit has said that an amino acid sequence is sufficient to describe the genus, so it is sufficient to claim the genus, even if it is not sufficient support for a claim to the

natural sequence per se. (*In re Wallach*, 71 USPQ2d 1939 (Fed. Cir. 2004), saying that, "the complete amino acid sequence of a protein may put one in possession of the genus of DNA sequences encoding it, and that one of ordinary skill in the art at the time the '129 application was filed may have therefore been in possession of the entire genus of DNA sequences that can encode the disclosed partial protein sequence, even if individual species within that genus might not have been described or rendered obvious.")

The very recent BPAI case cited above, *Falkner*, says that to satisfy the written description requirement, "it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation." Where the specification and claims refer to species such as *ccm* and *icr* that are known in the art, no further description is necessary under that standard. Since the specification provides written description for the invention that satisfies the standards in *Falkner*, and that supports the claims as they would have been understood by one of ordinary skill, this rejection can be withdrawn.

Claim Rejections under 35 U.S.C. 102

Claim 1 was rejected as allegedly anticipated by Kuhstoss, et al., cited on the IDS. According to the Examiner, Kuhstoss teaches "PKS genes containing modules such as a starter module (equivalent to a loading module), see page 231 of the reference. The starter module of the reference has a KS^Q, AT and ACP domain (see Figure 1 of the reference). Furthermore, Kuhstoss et al. teach that the AT domains in PKS type I systems select the appropriate stubstrate at each step in the synthesis. Therefore, the limitations of the claim is [sic] met by the reference."

The applicant traverses this rejection.

To anticipate a claim, a reference must set forth all of the limitations of the claim exactly as they occur in the claim. Kuhstoss describes a genetic construct having "starter module" in Figure 1, page 232. The "starter module" is one that initiates the sequence of reactions shown in the

biosynthetic pathway, denoted as 'A' in Figure 1. The biosynthetic pathway 'A' clearly begins with the step: "A, malonyl-CoA". That step is used to introduce a two-carbon unit onto acetyl-CoA, and it clearly uses malonyl-CoA, not ethyl malonylCoA. Thus the genetic construct in the Figure does not disclose a "loading module" comprising an "AT specific for ethylmalonyl CoA" as required by the claim.

The only disclosure of an ethylmalonyl CoA in Figure 1 seems to be in the fifth step of the biosynthetic pathway, which appears to correspond to Module 5 of the genetic construct, and is labeled with 'B' above one of the arrows in the biosynthetic sequence depicted in Figure 1. Module 5 does not include a KSQ group, and performs a substantially different role from the starter module; it is not a 'loading module'. Accordingly, Kuhstoss does not disclose all of the limitations of claim 1, because it fails to disclose a 'loading module' containing an acyltransferase (AT) specific for ethylmalonyl CoA. Therefore, this rejection can be withdrawn.

Obviousness-type Double Patenting Rejection

Claims 1 and 2 were rejected as allegedly obvious variants of the subject matter claimed in U.S. Patent No. 6,627,427, under the judicially-created obviousness-type double patenting doctrine.

This rejection is clearly improper: the rejected claims are two claims that were restricted out of the application from which U.S. Patent No. 6,627,427 issued. However, solely to advance prosecution, the applicant is providing a terminal disclaimer over that issued patent, which is co-owned by the assignee of the present application. Therefore, this rejection can be withdrawn.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 300622004810. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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